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14. ABSTRACT
Prostate cancer is the second leading cause of cancer death in men. Like other forms, prostate cancer exists in both sporadic and hereditary forms. A family history of prostate cancer and African-American ethnicity are two key factors that have been found to place men at increased risk for developing the disease. However, at-risk men exhibit low levels of prostate cancer risk-related knowledge, despite their increased risk as a group. Prostate cancer risk assessment provides an opportunity to weigh available information and make decisions about screening options; it also provides a window of opportunity to offer concrete instruction in specific prevention behaviors. While there is controversy over the benefits and liabilities associated with prostate cancer screening, there is agreement that at-risk men need to understand the issues related to prostate cancer risk management. Family members can help facilitate health-related behavior and may serve as an important, but underutilized, gateway into the health care system. Thus, guided by the Cognitive-Social Health Information Processing (C-SHIP) model, the current study will evaluate the impact of a communication message intervention tailored to the partners of at-risk men enrolling in prostate cancer risk assessment to facilitate screening adherence.

15. SUBJECT TERMS
Informed participation in prostate cancer risk assessment and detection; Theory-guided health risk communication; Interventions communication; Partner support and outreach; Health information processing in at-risk populations

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Table of Contents

INTRODUCTION

Prostate cancer represents a serious health issue for many men. Higher morbidity and mortality rates in this population may be due, in part, to lack of interest in prostate cancer risk assessment programs, as well as lower adherence to recommended detection and prevention guidelines for high-risk individuals. [1-3] Prostate cancer risk assessment programs provide an ideal opportunity to educate men about their risk status and inform them about the benefits and liabilities associated with available management options. Low participation in these programs suggests the need for innovative intervention message communications that target external channels of support and communication (i.e., spouses/partners). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available prostate cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model, [4, 5] the goal of the proposed study is to evaluate the efficacy of an innovative approach to enhancing participation in prostate cancer risk assessment among at-risk men through the use of psychoeducational, mail-home printed material oriented to the spouse/partner, an important support person. The printed material, culturally sensitive to the ethnicity of the at-risk man, provides the partner with structured communication strategies for addressing, in a preventive fashion, the proband's pattern of cognitive-affective barriers to risk assessment (i.e., proband risk-related perceptions; expectancies/beliefs; values/goals; and affect).

The specific aims are as follows:

Aim 1: To explore the efficacy of a partner-directed theoretically-based intervention in promoting prostate cancer risk assessment and knowledge among men at risk for prostate cancer.

Aim 2: To investigate the mediating role of theory-guided communication/cognitive-affective factors on participation in risk assessment among at–risk men and their partners.

Aim 3: To explore the moderating role of individual differences in attentional style (i.e., high vs. low monitoring) of the proband, as well as that of the partner, on the impact of the intervention.

In a randomized controlled trial, eligible probands (African Americans/First Degree Relatives with a spouse/partner) who contact PRAP at FCCC (N=300) will be randomized to receive either: 1) Standard Care (SC) alone, consisting of receipt of a pre-appointment, culturally sensitive mail-home patient-based educational video and a pre-appointment reminder call; or 2) SC plus the receipt of a pre-appointment, mail-home psychoeducational brochure directed to the spouse/partner (PBS). We will assess proband participation in the initial PRAP appointment and in the 6-week follow-up session, as well as risk-related knowledge. We hypothesize that men in the PBS condition will display higher rates of participation in risk assessment and greater levels of

knowledge than men assigned to SC, since the intervention prompts the active role of a critical social contact to promote and support health-related behavior.

In this context, the impact of the partner-directed intervention on outcomes is hypothesized to be mediated by changes in the dyad's communication pattern (i.e., frequency/responsibility), as well as by changes in the dyad's individual cognitive-affective processing patterns (i.e., perceived risk; self-efficacy and outcome expectancies; decisional conflict; and level of risk-related distress). These psychosocial mediators will be assessed at baseline (upon entry into PRAP) and at the initial PRAP appointment for attendees or at one-month following the missed appointment date for non-attendees.

We will also explore how monitoring attentional style, for both proband and partner, influences actual participation in prostate risk assessment and risk-related knowledge among at-risk dyads. We expect that high monitors will exhibit a cognitive-affective profile characterized by greater perceived vulnerability to disease, lower expectancies of control, less decisional conflict, and higher levels of risk-related ideation than low monitors.

Study findings will guide the future design of tailored interventions by identifying the psychosocial mediators and moderators that underlie effective risk communication between the proband and the critical support person. Results will be relevant to other cancer contexts where the risks are personal, probabilistic, and preference-based. The intervention is designed to be easily transportable and readily disseminable, providing outreach to critical support persons of at-risk individuals. Overall, this study will provide important data for implementing prostate cancer health-promotion interventions for all men on a broader scale.

BODY

For this year, the goal was to accomplish *Task 1*, *Task 2* and initiate *Task 3* as outlined in our Statement of Work. *Task 1* involved submitting the protocol for approval, conducting two focus groups (1 African American and 1 Caucasian) to provide feedback on the brochure, and finalizing all study measures. We subdivided this task into the following sub-tasks:

a. Submit Protocol to Institutional Review Boards (FCCC and DOD)
b. Convene with Consultants
c. Conduct Focus Groups and Analyze Focus Group Data (Phase I)
d. Revise, Finalize and Print Partner Brochures
e. Finalize Baseline and Follow-up Measures

Task 2 involved developing a system for participant tracking, data collection (i.e., a Computer Assisted Telephone Interview, and data entry. We subdivided this task into the following sub-tasks:

a. Establish a participant tracking system that is coordinated with PRAP tracking methods.
b. Develop a Computer Assisted Telephone Interview (CATI) system for collection of proband and partner assessments
c. Train research staff in study-specific consent process
d. Provide CATI training
e. Review procedures for on-site informed consent and interview processes

Task 3 involved study recruitment and data collection. Recruitment into the main study would begin, which would include consenting both proband and spouse/partner into the study. Once consented, each would be sent their respective materials (standard care materials, and/or psychoeducational brochure, if assigned to the intervention condition). We subdivided this task into the following sub-tasks:

a. Enroll eligible probands into the study
b. Consent and complete baseline assessment
c. Send them the Standard Care materials
d. Consent and complete baseline assessment for spouse/partner
e. Send them the psychoeducational brochure (if assigned to intervention condition)

To date, we have completed sub-tasks a, b, d and e from *Task 1* of the overall project (i.e., received approval from the FCCC IRB and DOD, convened with consultants, and finalized the brochures and measures). However, changes in staffing and study procedures and finalization of recruitment processes with the Prostate Risk Assessment Program staff have caused delays in the start-up of our study. This has pushed back our initial timeline for completion of our study. With regard to *Task 1*, we have re-evaluated sub-task c for the following reasons. First, in re-evaluating our existing focus group data with input from the Behavioral Research Core Facility at FCCC, we realized that we had sufficient input to proceed with the drafts of the written materials that we already had produced. Second, given the delays in start-up as outlined above, we were concerned about further delays in the accrual process into the study proper. Third, the pre-intervention focus groups (Phase I) would have been difficult to arrange given the time delay. We had originally counted on using a waitlist of name of couples who said they would be interested in participating in the focus groups; however, given the time delay, the waitlist of available persons interested in the focus groups was no longer available and alternate means of recruitment would delay the overall study. Therefore, we have decided to proceed directly with the main study (Phase II). A formal amendment is currently being drafted regarding the removal of the focus group portion (Phase I) of the study. The post-intervention focus groups (Phase III) will remain in the study.

With regard to *Task* 2, we have completed all sub-tasks as follows: 1) we have established a participant tracking system, 2) trained and reviewed all informed consent and interview procedures with the research staff, 3) completed development of the CATI and 4) completed staff training on the CATI system. Development of the Computer Assisted Telephone Interview (CATI) took 4 months longer than expected, because it

required a novel framework in order for us to be able to link the partner data with the proband data. This link is essential for ensuring that participant information will be viewed as a dyad and not as individual records for the purposed of participant tracking, follow-up assessments and data analysis. This newly developed CATI system is innovative and can be adapted for other projects in the future. The CATI system is designed to link multiple records to a single participant record, thus, in studies that call for enrolling partners or multiple family members, those records will be clustered together and easily accessible when working with a particular participant.

The sub-tasks of *Task* 3 have recently been implemented, involving putting the procedures for recruitment into place. To date, two participants have expressed interest in the study; however, they were not enrolled because they did not meet the initial eligibility criteria. We have met with personnel from the Prostate Cancer Risk Assessment Program to facilitate more efficient patient identification and referral into the study.

Further, an amendment was recently submitted to the DOD (submitted 8/7/06, official approval received 11/8/06) and to the FCCC IRB (submitted 8/28/2006 and approved 9/7/2006), requesting changes to the overall project. A summary of those changes are listed below:

1. All references to persons no longer affiliated with the project were removed.
2. Language in the recruitment section for Phase II of the protocol was changed to reflect the lack of feasibility of PRAP intake staff in recruiting participants for the study. Instead, PRAP staff will now only obtain interest and contact information. That information will be transferred to research personnel for formal recruitment and enrollment into the study.
3. Telephone recruitment scripts for research personnel were revised to reflect changes to the recruitment process.
4. Language in the Data Safety and Monitoring section of the protocol was changed to reflect the reporting responsibilities of the investigator to the sponsor (Department of Defense).
5. Revisions were made to all consent forms (main study and focus groups) such that they reflected any changes made in the protocol and changes requested by the sponsor.

KEY RESEARCH ACCOMPLISHMENTS

- Submitted an amendment to the Fox Chase Cancer Center Institutional Review Board requesting approval to revise the recruitment process for Phase II of the study. Approval from the FCCC IRB was received on 9/7/2006. Official approval from the DOD was received on 11/8/06.

- The Fox Chase Cancer Center Institutional Review Board study approval expires on 12/12/2006. An on-going/continuous review was submitted on 11/13/2006.

- Currently reviewing study measures and protocols

- Preparing and printing brochures and study measures

- Development of a novel CATI system for ease of participant tracking and data analysis for linked proband and partner information.

- Refined study recruitment procedures

REPORTABLE OUTCOMES

To date, no outcomes have been assessed and there are no publications or presentations to report.

CONCLUSION

Overall, we have made progress towards reaching our goals. However, due to start-up delays, we were unable to arrange the Phase I focus groups as outlined. Further, finalization of the brochure and measures was completed without input from the Phase I focus groups, because we realized that we had sufficient information to complete this task from prior work with the Behavioral Research Core Facility at FCCC. This has allowed us to proceed directly to Phase II of the study. An amendment is being drafted concerning these changes. Problems with the recruitment process for Phase II were realized and adequately resolved, thus allowing us to begin that process. In addition, an innovative Computer Assisted Telephone Interview (CATI) model was developed for this study and can be adapted for use in future projects. Currently, efforts are underway to bring this study up to date, as outlined in the Statement of Work. We anticipate no further obstacles in conducting our study as scheduled, and foresee no further delays in the progress of this project. We expect that we will achieve our overall recruitment goals and successfully complete the study as outlined.

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APPENDICES - None